REMARKS

Applicant respectfully requests entry of the amendment and reconsideration of the claims. Claims 1-24 are pending. Claims 1, 2, 7, and 14-19 have been amended. Claims 23 and 24 are new. The amendment is supported by the specification, for example, at page3, lines 4-9, page 4, lines 20-24, page 7, lines 7-15, the working examples, and claim 1 as originally filed, and does not introduce new matter.

Rejections under 35 U.S.C. § 112

Claims 1, 2, 7, and 14-19 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Claims 2 and 14-19 have been amended to clarify that the frame of reference for the ratio is "by weight". Claim 7 has been amended to remove the trademark. Applicant submits the claims as amended fully comply with § 112, second paragraph. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 1-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Walling (U.S. 6,586,449) in view of Ferno (U.S. 3,845,217). Applicant respectfully traverses the rejection.

The Office Action acknowledges that Walling does not disclose the specific order of method steps recited in the claims or a chewing gum. However, the Office Action alleges it would have been *prima facie* obvious to modify the process disclose in Walling to arrive at the claimed methods. Applicant does not agree as the claims are supported by unexpected results.

Applicants submit a nicotine delivery product which has the same nicotine loading capacity as the compositions disclosed in Walling, but a nicotine release rate of at least 80% was an unexpected and surprising result. The specification discloses a nicotine delivery product that comprises a nicotine release rate of at least 80% over a 10 minute period. See the specification, for example, at page 3, lines 4-9. The Applicant has tested products produced by the method of the present invention and these results are shown below in Table A. The polyol used was

glycerol. Table A shows the nicotine release over a 10 minute period as per the U.S.P. test method.

Table A

	AVG	SD	RSD	N
July 2009 testing				
A	81.7	1.2	1.5	6
B	80.2	3.1	3.9	9
September 2010 testing	78.6	2.4	3.0	118

For comparison purposes, the nicotine release properties of products produced by the Walling method are shown in Table 1 at columns 3 and 4 of Walling. Walling determined the nicotine release properties using the same U.S.P. test method used to obtain the data in Table A above. For glycerol, Walling discloses 71% release of nicotine which is almost 10% less nicotine release than in the claimed nicotine delivery products. Regardless of which polyol was used, the highest nicotine release value reported in Walling was 77% (obtained with sucrose). Walling does not provide any evidence that the methods disclosed therein are suitable for producing a composition having nicotine release greater than 77%.

The Examiner also alleges it would have been obvious to change the order of the process steps in Walling to arrive at the present claims as Ferno discloses that the release rate of nicotine can be varied by varying the amount of nicotine bound to the cation exchange resin and that mixing the nicotine with the exchange resin in the first step would allow more nicotine to be bound to the resin before the addition of the polyol. Applicant does not agree.

It is well established that "a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02 citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983) *cert. denied*, 469 U.S. 851 (1984). It is improper to combine references where the references teach way from their combination. MPEP § 2145(X)(D)(2) citing *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir.

1983). Walling discloses that the nicotine release characteristics of a chewable smoking substitute, such as those disclosed in Ferno, are not sufficient as such gums are only marginally effective because nicotine release is small and in reduced amounts. See Walling at col. 1, lines 41-50. In order to obtain a release rate of 70% within 10 minutes, Walling discloses that it is necessary to combine the polyol with the cation exchange resin **before** admixture with nicotine. See col. 2, lines 56-58. Walling therefore specifically teaches away from mixing the nicotine with the polyol prior to the cation exchange resin.

The nicotine delivery products disclosed by Applicant have the same nicotine loading capacity as the compositions disclosed in Walling. Contrary to the assertions in the Office Action, there is no teaching or suggestion in Ferno or Walling that adding more nicotine to the resin would enhance the rate of nicotine release from the resin. The enhanced nicotine release is a function of the polyol. The amount of nicotine in the Walling product is already at least 50% greater than the amount of nicotine in the product disclosed in Ferno (0.1 to 10% nicotine by weight, preferably 0.5 to 2 %; col. 8, lines 56-60), so there is no motivation as alleged in the Office Action to mix the nicotine with the exchange resin (as taught by Ferno) prior to addition of the polyol. Therefore, neither Walling nor Ferno discloses or suggests any advantage to mixing the nicotine with the cation exchange resin prior to addition of the polyol. Walling specifically teaches away from such a method for the reasons discussed above.

In view of the foregoing, Applicant submits the cited combination of references fails to renders the claims obvious as the claims are supported by unexpected results. The test results provided by Applicant show that an unexpected effect (i.e. increase in nicotine release) is obtained by the order of steps recited in the claims. Withdrawal of the rejection is respectfully requested.

Double Patenting

Claims 1-22 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 6, 10-15, and 19-22 of Application No. 10/921,199. Although the rejection cites Application No. 10/921,199, Applicant believes the Examiner intended to recite Application No. 11.921,199.

Applicant acknowledges the rejection and request that the rejection be held in abeyance until allowable subject matter is indicated.

If a provisional non-statutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications and the later-filed application is rejectable on other grounds, the Examiner should withdraw the provisional ODP rejection and permit the earlier filed application to issue as a patent without a terminal disclaimer. MPEP § 804(I)(B)(1). Applicant notes that the present application was filed on March 16, 2007, while copending Application No. 11/921,199 was filed on November 21, 2008. The present application is therefore the earlier filed of the two applications.

Conclusion

In view of the above amendments and remarks, Applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

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Eric E. DeMaster
Reg. No. 55,107
EED:jrm

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